

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES**

In re Application of: Najdek, et al.

Serial No.: 10/618,803

Group Art Unit: 1616

Filed: July 14, 2003

Examiner: Webman, Edward

For: DUAL-PHASE COSMETIC COMPOSITION

APPELLANT'S BRIEF PURSUANT TO 37 CFR 41.31

Commissioner For Patents
Attention: Board of Patent Appeals and Interferences
Alexandria, Virginia 22313-1450

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1-5 and 7-22 in the present application in the decision of December 28, 2007.

REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is E-L Management Corp., the assignee of the application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

STATUS OF THE CLAIMS

Claims 1-5 and 7-22 remain finally rejected and pending in this application. Claim 6 has been cancelled. Claims 23 and 24 have been withdrawn. The appealed claims are claims 1-5 and 7-22 as presented in the Appellants' Preliminary Amendment, filed on October 25, 2007, which followed the filing, on October 5, 2007, of an RCE. The submission of October 25, 2007 was considered and entered by the Examiner, as noted in the Office Action Summary of December 28, 2007, although the cancellation of claim 6 in the submission, as redundant over claim 1, may not have been appreciated by the Examiner. The appealed claims are again presented herewith in the Claims Appendix.

STATUS OF AMENDMENTS

There has been no amendment of the claims following the final rejection of December 28, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention of independent claim 1 is a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a film forming agent.

The invention of independent claim 8 is a liquid dual phase makeup removal composition comprising an oil phase and an aqueous phase in which the oil phase and aqueous phase are present in a ratio of from about

30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent, an effective amount of a non-cationic film forming agent.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The Appellants have previously stipulated that the rejection of the claims on the ground of nonstatutory obviousness –type double patenting will remain in effect until such time as the claims are amended or a terminal disclaimer is filed. The claims stand rejected as being unpatentable over claim 11 of U.S. Patent No. 6,649,174, on the ground of nonstatutory obviousness –type double patenting, since although the conflicting claims are not identical, they are not patentably distinct from each other because the instant independent claims encompass the patent claim regarding the film forming agent and ratio. A terminal disclaimer has been filed on August 1, 2008.

The remaining issues are:

- (1) whether claims 1, 2, 4, 5 and 7 are unpatentable over U.S. Patent No. 5,468,496 to Touzan *et al.* (hereinafter referred to as “the ‘496 reference”), in view of U.S. Patent No. 4,980,155 to Shah *et al.* (hereinafter referred to as “the ‘155 reference”) under 35 U.S.C. §103(a);
- (2) whether claims 8, 9 and 11-19 are unpatentable over the ‘496 reference in view of the ‘155 reference;
- (3) whether claims 1, 2, 4, 5, 7 and 21 are unpatentable over U.S. Patent No. 5,871,758 to Nagy *et al.* (hereinafter referred to as “the ‘758 reference”) in view of U.S. Patent No. 4,438,095 to Grollier *et al.* (hereinafter referred to as “the ‘095 reference”) under 35 U.S.C. §103(a); and
- (4) whether claims 8, 10-20 and 22 are unpatentable over the ‘758 reference in view of the ‘095 reference.

Specifically, the questions are:

- (1) whether one of ordinary skill in the art would have been led to add a protective colloid, e.g., polyvinylpyrrolidone (PVP) or polyvinylpyrrolidone/vinyl acetate (PVP/VA) copolymer, also known as film formers, to the composition of the ‘496 reference for the beneficial effect of maintaining colorants in suspension in view of the ‘155 reference, and thus arrive at the Appellants’ invention which comprises a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a film forming agent;
- (2) whether one of ordinary skill in the art would have been led to add a protective colloid, e.g., polyvinylpyrrolidone (PVP) or polyvinylpyrrolidone/vinyl acetate (PVP/VA) copolymer, also known as film formers, to the composition of the ‘496 reference for the beneficial effect of maintaining colorants in suspension in view of the ‘155 reference, and thus arrive at the Appellants’ invention which comprises a dual phase liquid

cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a non-cationic film forming agent;

(3) whether one of ordinary skill in the art would have been led to add a cationic conditioning agent, e.g., a vinyl pyrrolidone-acrylamide copolymer, also known as a film former, to the composition of the '758 reference for the beneficial effect of introducing a conditioning agent to the composition in view of the '095 reference, and thus arrive at the Appellants' invention which comprises a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a film forming agent; and

(4) whether one of ordinary skill in the art would have been led to add a cationic conditioning agent, e.g., a vinyl pyrrolidone-acrylamide copolymer, also known as a film former, to the composition of the '758 reference for the beneficial effect of introducing a conditioning agent to the composition in view of the '095 reference, and thus arrive at the Appellants' invention which comprises a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a non-cationic film forming agent.

ARGUMENT

I. Rejections under 35 USC §103(a)

A. Claims 1, 2, 4, 5 and 7

For purposes of patentability, claims 1, 2, 4, 5 and 7, drawn to the first outstanding issue of the present Appeal, are grouped together. Specifically, the claims are grouped together as they apply to the rejections based on 35 U.S.C. §103(a). The outstanding issue is whether claims 1, 2, 4, 5 and 7 are unpatentable over the '496 reference, in view of the '155 reference under 35 U.S.C. §103(a). The rejection, as stated in the final decision of December 28, 2007, in relevant part, is as follows:

“Touzan et al teach a two phase composition for cleansing containing a demixing agent (title, abstract). An aqueous and separate oily phase in a ratio of 30:70-60:40 is disclosed (abstract). Isohexadecane, liquid paraffins, and silicone oils including cyclopentadimethylsiloxane are disclosed (column 4 lines 1-20). Colorants are specified (column 4 line 25).

Shah et al teach a polyvinylpyrrolidone/vinyl acetate copolymer at 1-5% to maintain pigments in suspension (column 4 lines 37-57). Applicants disclose this polymer on page 2 line 33.

It would have been obvious to one of ordinary skill to add a polyvinylpyrrolidone/vinyl acetate copolymer to the composition of Touzan et al for the beneficial effect of maintaining colorants in suspension in view of Shah et al.

Applicants argue that one of ordinary skill would not add PVP to the composition of Touzan et al as a suspension agent because only a mere 0.05% colorant is disclosed, compared to the large amounts of colorant in Shah et al. The implication is that PVP is only effective for large amounts of colorant. However, this is mere speculation. Applicant also argue that demixing compositions are difficult to make, therefore, one of ordinary skill would not add PVP, a known suspension and emulsion stabilizer, because it would interfere with the demixing function. However, Touzan et al already use emulsifying agents, namely the many surfactants cited at column 2 line 36 et seq. that is, one of ordinary skill, reading that Touzan et al, is already using such agents, it argue, would be motivated to accommodate the addition of another, such as PVP...”

Prior to addressing the merits of the rejection, the Appellants wish to restate the nature of the present invention. The present invention is directed to a dual phase liquid cosmetic composition comprising an oily phase and an aqueous phase in a ratio of 30:70 to 70:30, and a demixing agent. The phases are separate from one another before and after being mixed at the time of use. The dual phase composition, prepared with a film former, such as PVP or a copolymer thereof as the demixing agent emulsifies rapidly and uniformly upon vigorous shaking and demulsifies completely upon resting. The vigorous shaking results in the formation of micelles, both the water-in-oil and oil-in-water types, containing the film former. Although both cationic and non-cationic film formers can be used in the present invention as the demixing agent, when cationic film formers are used, more

micelles are formed initially, and, due to their higher concentration, they tend to repel one another, bumping apart, resulting in a more rapid separation of the phases. The dual phase formulation is therefore only in the emulsified state temporarily, and upon resting, returns to its demixed or two phase state. That a film former, a known suspension/dispersion agent and emulsion stabilizer, could be used as a demixing agent to facilitate rapid separation of the phases in a two phase emulsion, is considered counterintuitive and therefore both surprising and unexpected.

The '496 reference

The '496 reference describes a dual phase cleansing composition having an aqueous phase and an oily phase. The aqueous phase contains, as a demixing agent, a specific class of surfactant, the alkyldimethylbenzylammonium ("benzalkonium") chlorides. The reference does not disclose or suggest the presence of a film former, nor the use of film formers as demixing agents. The Examiner relies on the disclosure of film formers in the '155 reference in an attempt to establish *prima facie* obviousness of the present invention.

The '155 reference

The reference discloses a dual phase composition, and is principally directed to a product which emphasizes color. The two phases are both aqueous and therefore miscible. One of the aqueous phases is a gel phase, while the other phase is an intensely colored color phase. The color phase is manipulated and disposed in a container against a background of the gel phase such that the color phase appears completely engulfed in the gel. As the two phases are both aqueous and therefore, miscible, the two phases are kept separated before use to provide an aesthetically attractive product in which the color phase does not bleed into the gel phase, and in which the product highlights the critical color emphasis of the composition. The phases are only mixed at the time of use to form a homogenous composition, and, once mixed, the two phases are never demixed. As further taught in the reference, the color phase contains a protective colloid, such as PVP or VP/VA copolymer, which acts like an emulsifier by coating the surfaces of pigment particles in the dispersed phase, thus preventing coalescence and subsequent separation, and keeping the pigment particles from bleeding into the gel phase.

Combined teachings of the '496 and the '155 references

Under a correct analysis for obviousness, the question is whether the proposed combination (modified product), based on the disclosure in the references, would have been obvious to a person of ordinary skill in the art. In other words, would the person of ordinary skill in the art have considered, at the time of the invention, whether there was any need or problem in the cosmetic field addressed by the references which could provide any reason for combining the elements in the manner claimed? It is the Examiner's assertion that one of ordinary skill in the art would have been motivated to modify the dual phase compositions of the '155 reference, by the addition of PVP or PVP/VA copolymer, for the purpose of maintaining a substantial amount of colorant in suspension, as taught in the '496 reference, and thus arrive at the present invention. The Appellants cannot agree with the

Examiner that a person of ordinary skill in the art would have found it desirable to make the proposed combination for the following reasons.

The '155 teaches that the PVP or PVP/VA copolymer, used as a protective colloid, would be needed to disperse 1 to 60 weight percent pigment (based on the total weight of the color phase composition) to prevent precipitation of the colorants, and to keep the pigment from bleeding into the gel phase. Further, as the Appellants noted in response to the previous office action, in all of the many examples in the reference, 30 to 40 weight percent pigment is employed. These are intensely colored compositions. The reference thus teaches or suggests that the PVP or PVP/VA copolymer would only be required to suspend a substantial amount of pigment in an aqueous phase, and would not be needed to disperse relatively small amounts of pigment, such as that amount, 0.05% pigment, disclosed in a single example in the '496 reference. Therefore, unless a substantial amount of pigment (i.e. at least 1%, and typically, 30-40%) were being introduced into the dual phase composition of the '496 reference, the '155 reference suggests that introduction of a protective colloid, e.g. PVP/VA copolymer would not be indicated. Thus, the Appellants are not implying, in contrast to the statement by the Examiner, that the protective colloid would not be effective to disperse small amounts of colorant, but merely that the '155 reference teaches or suggests that the protective colloid is not indicated for suspending small amounts of colorants.

Furthermore, the '496 reference is principally directed to surfactant-containing/cleansing compositions. It is the Appellants understanding that cleansing products do not tend to be intensely colored. Additionally, none of the compositions in the examples, which include two eye makeup-removal formulations, a body lotion and a sun protection lotion, contains a significant level of colorants, and it is the Appellants' position that introducing a significant amount of pigment to these compositions would be unusual, and would not solve any need or problem in the cosmetic arts. For example, it is highly questionable as to whether a consumer would want to use a body lotion which is intensely green or red in color, or use a product containing a substantial level of blue or orange dye in contact with the eyes. If this was the case, such products would likely already have been introduced to the marketplace. There is no disclosure or suggestion in the references that the proposed modification (i.e. introducing a substantial amount of pigment into the dual phase composition) would be desirable for the types of products contemplated by the '496 reference, nor that such addition would solve any longstanding problem in the cosmetic arts.

Nevertheless, it is the Examiner's position that, in the event that it was deemed desirable to add a relatively large amount of colorant and PVP or PVP/VA copolymer to the compositions of the '496 reference, one skilled in the art could reasonably predict that this could be done successfully without negatively affecting the properties of the '496 dual phase compositions. Such a statement by the Examiner, however, is a mere unsupported conclusion and is not technically sound. Introducing a further stabilizing agent, i.e., a dispersing/suspending agent (e.g. PVP or PVP/VP copolymer) into the dual phase compositions in the '496

reference is counterintuitive; that is, if one having ordinary skill in the art of cosmetic formulation had any prediction whatsoever about the efficacy of the modified composition, it would be that the additional stabilizing ingredients would negatively affect the properties of the '496 composition, in particular, its demixing capability. The surprising advantage of the product of the '496 reference, as well as that of the present invention, is that the product remains only temporarily in the mixed or emulsified state, and that, due to the presence of the demixing agent, the product returns quickly to the demixed or two phase state. The '155 reference, in teaching the use of PVP or PVP/VA copolymer to suspend pigments, thus stabilizing the composition, teaches away from the achievement of the present invention wherein the film former performs a demixing function. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the claimed invention. *In re Gurley*, 31 USPQ2d 1130, 1131 (CAFC 1994).

A further reason that one of ordinary skill in the art would not have been led to make the combination proposed by the Examiner is that the prior teaches against the random mixing of ingredients in formulating a successful, that is, properly functioning, two phase composition, and in particular, a two phase composition which emulsifies readily on shaking but whose constituents segregate rapidly on standing, as discussed in the introductory paragraphs of the '496 reference (and in the introductory paragraphs of cited U.S. Patent No. 5,871,758 to Nagy *et al.*). As discussed in these patents, a number of factors must be considered. At the very least, such compositions call for a certain balance of surfactants/emulsifiers and demixing agents to achieve the desired result. Therefore, in contrast to the position of the Examiner that, "...as the '496 reference already uses emulsifying agent, namely the many surfactants...one of ordinary skill, reading that Touzan *et al.*, is already using such agents, would be motivated to accommodate the addition of another, such as PVP.", the Appellants assert, first, that PVP is not just another surfactant, and in fact, is not a surfactant at all, and further, that it would be considered counterintuitive by those skilled in the art of cosmetic formulation to merely throw into the dual phase composition of the '496 reference another ingredient, but moreso when that additional ingredient is a stabilizing agent, e.g. a suspension agent, a dispersant, an emulsion stabilizer, etc., with any reasonable expectation that such additional ingredient would not adversely affect at least the demixing capability of the product by further stabilizing the mixed/emulsified form of the composition. The only reasonable prediction one of ordinary skill in the art could make about the addition of PVP to the compositions of the '496 reference would be that the length of time the formulation remained in the emulsified/mixed state would be increased, thus delaying the separation of the phases into the demixed state.

In the Advisory Action of July 18, 2008, the Examiner states the following:

"The request for reconsideration has been considered but does NOT place the application in condition for allowance because: for the reasons stated in the office action mailed on December 28, 2007. Applicants argue that (1) that the

'155 reference suggest that the protective colloid would not be needed for relatively small amounts such as that amount exemplified in '496 of 0.05%. Applicants further argue that there is no disclosure or suggestion that introducing substantial amount of pigment would be desirable. Applicants argue that (2) introduction of a further stabilizing/dispersing agent is counterintuitive and that adding these sort of ingredients would negatively affect the properties of the '496 composition, in particular the demixing capability of the composition....

Regarding applicants' first argument, the '496 references indicates that colorants, which are common in the art can be added. While they only exemplify one percentage, this does not mean that only one percentage is acceptable. One of ordinary skill in the art would have been motivated to optimize the amount of colorant added depending on the desired color of the product. As taught by the '155 reference, when incorporating higher amounts (1% or greater) of pigment it is advantageous to add a protective colloid to maintain the pigment in suspension. Therefore, one of ordinary skill would have been motivated to add this component. Regarding applicants' second argument, it is unclear to the examiner how the addition of the protective colloid is counterintuitive. This component is added to a dual phase composition to maintain the pigment in suspension. It is unclear how maintaining the pigment in suspension affects the composition ability to demix. 'The arguments of counsel cannot take the place of evidence in the record.'....Applicant has not proved any factual evidence establishing unobviousness."

The Examiner again suggests that the addition of colorants to cosmetic compositions is common, so that introducing a large amount of colorants together with protective colloid to the '496 composition would be obvious to those skilled in the art. Nevertheless, as Appellants discussed above, the incorporation of colorants and protective colloid into the '496 reference formulations, which are principally cleansing compositions and lotions for application to the skin, solves no problem or need in the art known to the Appellants. Moreover, the Appellants are unaware of any intensely colored compositions of this sort, and suggest that these are not desired by consumers.

As to the Examiner's confusion over how the addition of the protective colloid to the '496 dual phase composition could be counterintuitive, the Appellants have argued above that, even were those skilled in the art initially led to make the combination for the reason proposed by the Examiner, those skilled in the art ultimately would not have made the combination, since the addition of a protective colloid, that is, a stabilizing agent; e.g., a suspension/dispersion agent and emulsion stabilizer, into the two phase compositions of the '496 reference, would be predicted to delay the demixing process by further stabilizing the mixed/emulsion stage of the product. It is the Appellants' position that the resulting product would either fail to function in the intended manner or that its demixing efficacy would be severely compromised. As factual evidence establishing the Appellants' position, as requested by the Examiner, one need only look at the functions of PVP in the CTFA on-line InfoBase. The functions listed for PVP are indicated as "Binders; Emulsion Stabilizers; Film Formers; Hair fixatives; Suspending Agents – Nonsurfactant". This supports the Appellants' position that the person of ordinary skill in

the art would not be led to introduce a material such as PVP into the '496 reference formulations, since an emulsion stabilizing/suspending/dispersing agent function of PVP would be expected by those of ordinary skill in the art to compromise the demixing efficacy of the '496 formulation.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. (*KSR International Co. v. Teleflex Inc.*, 82 USPQ 2d 1385, 1396 (US 2007)). It is well established law that when an applicant demonstrates substantially improved results ... and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary (*In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995)). Furthermore, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984). Appellants assert that in view of the cited references, and the knowledge of those skilled in the art at the time of the invention, it is considered both surprising and unexpected that a film forming agent, in view of its typical function as a stabilizing agent, e.g., a suspending/dispersing agent and emulsion stabilizer, could be used as a demixing agent in a two phase composition without negatively affecting the demixing capability of the two phase system.

B. Claims 8, 9 and 11-19

For purposes of patentability, claims 8, 9 and 11-19, drawn to the second outstanding issue of the present Appeal, are grouped together. Specifically, the claims are grouped together as they apply to the rejections based on 35 U.S.C. §103(a). The outstanding issue is whether claims 8, 9 and 11-19 are unpatentable over the '496 reference, in view of the '155 reference under 35 U.S.C. §103(a). The rejection, as stated in the final decision of December 28, 2007, is provided above, with regard to the discussion of claims 1, 2, 4, 5 and 7. A summary of each of the cited references and their combined teachings also is presented above. Additionally, it is to be noted that the '155 reference also discloses, as protective colloids, in addition to PVP and PVP/VA copolymer, non-cationic cellulose ethers (column 4, lines 37-50). It is the Appellants' position, however, that all of the arguments presented above (with regard to the discussion of the patentability of claims 1, 2, 4, 5 and 7) as to why one of ordinary skill in the art would not have introduced a protective colloid, generally, into the dual phase formulations of the '496 reference, as taught by the '155, are equally as applicable to the introduction of a non-cationic protective colloid into the dual phase composition. Moreover, the non-cationic film formers recited in claims 8 and 9 in the present application, are neither disclosed nor suggested in the '155 reference.

C. Claims 1, 2, 4, 5, 7 and 21

For purposes of patentability, claims 1, 2, 4, 5, 7 and 21, drawn to the third outstanding issue of the present Appeal, are grouped together. Specifically, the claims are grouped together as they apply to the rejections based on 35 U.S.C. §103(a). The outstanding issue is whether claims 1, 2, 4, 5, 7 and 21 are unpatentable over “the ‘758 reference” in view of the ‘095 reference”, under 35 U.S.C. §103(a). The rejection, as stated in the final decision of December 28, 2007, in relevant part, is as follows:

“Nagy et al teach a makeup removing composition comprising two phases and a demixing agent (abstract). A 30:70-70:30 ratio of oil to aqueous phase is disclosed (column 3, lines 12-14). Mixtures of cyclic silicones, dimethicone and a volatile C16 paraffin are specified (column 4, lines 33-53).

Grollier et al teach two phase compositions comprising a cationic polymer for skin conditioning (abstract). Vinyl pyrrolidone-acrylamide copolymers are specified at 0.2-50% (column 8, lines 1-26, column 9, lines 20-24). Dimethylaminoethylmethacrylate is disclosed (column 8 line 59). Applicants disclose PVP/dimethylamino ethylmethacrylate on page 2 line 32.

It would have been obvious to one of ordinary skill to add a vinylpyrrolidone-acrylamide copolymer to the composition of Nagy et al to achieve the beneficial effect of a skin conditioner in view of Grollier et al.

Applicants make the same argument here as in their response to the first 103, regarding the difficulty of making demixing compositions. However, here, Nagy et al teach hair conditioners (column 4 line 9). The cited Grollier et al polymers are such compounds. Thus, it is argued, one of ordinary skill, reading Nagy et al, would be motivated to accommodate the addition of the Grollier et al polymers. Applicants also argue that Nagy et al teach demixing agents in the aqueous phase. However, the motivation to combine concerns a skin conditioning agent, not a demixing agent. Applicants also argue that Grollier et al teach against addition to the oil phase. However, Grollier et al is referring to anhydrous compositions...”

The ‘758 reference

The ‘758 reference addresses the problems encountered in the art in attempting to formulate a liquid dual phase cleansing composition comprising an oil phase and an aqueous phase, and, as a demixing agent, a specific class of cationic surfactant which is a quaternary nitrogen-containing ether substituted alkoxyated alkyl glucoside. The aqueous and oily phases are mixed temporarily at the time of use and rapidly demixed. The demixing agent, being water-soluble, is preferably added in the aqueous phase of the composition. The reference does not teach or suggest the Appellants’ film formers or their use as demixing agents in such a dual phase composition. The Examiner relies on the ‘095 reference for that disclosure in an attempt to establish *prima facie* obviousness of the instant invention.

The ‘095 reference

The ‘095 reference is concerned with the problem of formulating a conditioning composition, particularly for the hair, which does not leave hair with the greasy appearance and feel attributed to purely oil-based compositions, and how to formulate a useful composition incorporating the conditioning benefits of both cationic

polymers and oils, when it is known that the cationic polymers have severely limited efficacy when incorporated into the oils. Described in the patent is a product including two distinct and separately packaged compositions that are only mixed at the time of application, so as prevent the contact of the cationic polymers with the oils. The compositions are shaken to disperse the aqueous composition, containing the cationic polymer, into the oily composition. Once mixed for use, the product is not demixed. The cationic polymer may be, for example, a vinylpyrrolidone acrylate or methacrylate copolymer.

Combined teachings of the '758 and '095 references

It is the Examiner's position that one skilled in the art would be motivated to introduce the cationic compounds, e.g. a vinyl pyrrolidone-acrylamide copolymer, of the '095 reference, into the dual phase composition of the '758 reference to provide a skin conditioning benefit.

When considering the teachings in the '095 reference in their entirety, the Appellants cannot agree with the reasoning of the Examiner. The cationic compound-containing aqueous composition in the reference is kept separate from the oily composition until the time of use for the reason that the desirable properties of the cationic polymers will be compromised by prolonged contact with the oil. Specifically, at column 1, lines 46-57, of the '095 reference, it is taught that, although it is possible to incorporate the cationic polymers in the oil, the effectiveness is very slight because their characteristic adherence to the skin or hair is inhibited in the oily medium. It follows that, if the cationic conditioning polymer of the '095 reference were introduced into the dual phase composition of the '758 reference, where, in use, the composition is continually mixed and demixed, one of ordinary skill in the art would predict that, upon the repeated contact of the cationic polymer with the oily phase, the conditioning benefit imparted to the composition by the cationic polymer would be expected quickly to become negligible. Therefore, although the Examiner alleges that one skilled in the art would be motivated to combine the teachings of the '758 and the '095 references and modify the compositions of the '758 reference to include the conditioning agents (i.e. cationic polymers) of the '095 reference to achieve the present invention, the Appellants assert that the disclosure in the '095 reference clearly teaches away from doing so. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the claimed invention. *In re Gurley*, 31 USPQ2d 1130, 1131 (CAFC 1994).

One skilled in the art of formulating two phase compositions would not have been led to combine the teachings of these references for yet another reason. The products of the '758 reference and the '095 reference clearly possess entirely different properties, the former is a dual phase composition including aqueous and oily phases which are mixed at the time of use to form a temporary emulsion and which rapidly demix. The latter product includes two compositions which are maintained separately to avoid contact between the cationic polymers and oil, and when mixed at the time of use, form dispersions of an aqueous phase in an oily phase and do not demix. As discussed above, with regard to the '496 and the '155 references, those of ordinary skill in the

art of formulating emulsions would appreciate that formulating a stable emulsion is a formidable task and that one does not easily introduce a further ingredient into such stable emulsion without some prediction as to the behavior of that ingredient in the stable emulsion composition; that is, some indication that the further ingredient will not upset the delicate balance achieved in the stable emulsion. Similarly, those skilled in the art would appreciate that formulating a two phase composition which forms an emulsion only temporarily upon mixing and rapidly demixes cannot be any less difficult. The Examiner again is referred to the introductory paragraphs of the '758 reference in which it is discussed that a number of factors are to be considered in making a successful dual phase product. For this additional reason, those skilled in the art would not have been led to introduce cationic conditioning agents, as taught in the '095 reference into the dual phase composition of the '758 reference with a reasonable prediction as to the behavior of the conditioning agents in the composition.

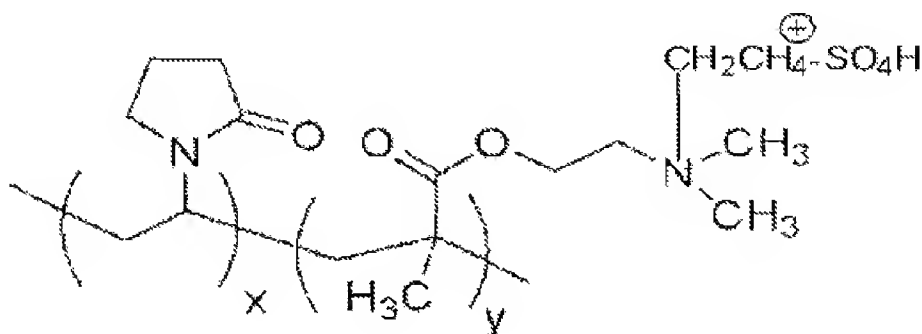
In the Advisory Action of July 18, 2008, the Examiner states the following, in relevant part:

“...Applicants argue that (3) the effectiveness of the cationic polymer is slight and that the instant invention and the '758 reference rapidly mix and demix. Applicant argues that (4) formulating a stable emulsion is a formidable task and that without some predication as to the behavior of that ingredient in stable emulsion that the incorporation of that ingredient would not upset the delicate balance achieved in the stable emulsion.

Regarding applicants' third argument, the '758 utilizes cationic surfactants as the demixing agents, therefore one of ordinary skill in the art would have a reasonable expectation that the cationic polymers of the '0895 reference would behave the same way when incorporated in to the '758 reference. Regarding applicants' fourth argument, the '758 reference clearly indicates that cationic surfactants can be utilized in the invention, therefore one of ordinary skill in the art would not expect that they would upset the delicate balance achieved in a stable emulsion. Furthermore, applicants' have not provided any factual evidence that the incorporation of the cationic polymers of '095 into the composition of '758 would result in an unstable composition. .”

The Appellants do not argue, as the Examiner states, that the effectiveness of the cationic polymers is slight, but that the efficacy of the cationic polymers is slight in the presence of oil, as disclosed in the '095 reference. Notwithstanding that this disclosure is found in the '095 reference, the Examiner appears to take the position that, as both the cationic surfactant of the '758 reference and the cationic polymer of the '095 reference are “cationic”, their behaviors must be similar, and as such, the cationic polymers should behave as do the cationic surfactants in the '758 reference. This position is technically unsound. Those of ordinary skill in the art know that a surfactant consists of a hydrophobic (non-polar) hydrocarbon “tail” and a hydrophilic (polar) “head” group. This structure is the key to their behavior. In simplest terms, surfactants are soluble in both organic solvents and water, reducing the interfacial tension between the oil and water by adsorbing at the liquid-liquid interface and making

emulsification possible. While the head (e.g. quaternary ammonium-containing) of cationic surfactants is positively charged, the tail has no charge. On the other hand, cationic conditioning polymers, such as PVP and copolymers thereof, e.g., copolymer of vinylpyrrolidone and dimethylaminoethyl methacrylate (Polyquaternium 11) mentioned by the Examiner, do not have both hydrophobic and hydrophilic ends, and as discussed above, such polymers are nonsurfactants. As factual evidence establishing the Appellants' position, as requested by the Examiner, one need only look at the structure of PVP in the CTFA on-line InfoBase or the structure for Polyquaternium 11 which appears below.



Finally, the Appellants are not arguing that cationic polymers would be expected to upset the delicate balance achieved by an emulsion. On the contrary, the presence of cationic polymers in the formulations of the '496 reference may be expected to further stabilize the mixed/emulsion form of the composition by delaying demixing.

D. Claims 8, 10-20 and 22

For purposes of patentability, claims 8, 10-20 and 22, drawn to the fourth outstanding issue of the present Appeal, are grouped together. Specifically, the claims are grouped together as they apply to the rejections based on 35 U.S.C. §103(a). The outstanding issue is whether claims 8, 10-20 and 22 are unpatentable over "the '758 reference" in view of the '095 reference", under 35 U.S.C. §103(a). The rejection, as stated in the final decision of December 28, 2007, is presented above, with regard to the discussion of claims 1, 2, 4, 5, 7 and 21. A summary of each of the cited references also is presented above. The Appellants have noted that the Examiner has not addressed a specific limitation of claims 8, 10-20 and 22; that is, where the demixing agent is a non-cationic film forming agent. As the '095 reference discloses only cationic conditioning agents, the combined teachings of the '758 and '095 references cannot result in the Appellants invention, as recited in claims 8, 10-20 and 22, which require a non-cationic film former as the demixing agent.

For all of the above reasons, it is considered that the Examiner has not established a *prima facie* case of obviousness of the present invention, and that independent claim 1 is patentable over the references cited. Claims 2, 4, 5, 7 and 21 depend from and include all of the limitations of claim 1 and are therefore patentable for the same reasons as is claim 1. Dependent claim 2 is a particularly preferred embodiment of the invention which recites preferred film formers for use in the invention. Dependent claim 5 describes a further embodiment of the invention which specifies the range of the amount of the film former in the composition. Dependent claim 7 recites a preferred ratio of the oil to aqueous phases. Independent claim 8 calls for a non-cationic polymer as the demixing agent. Claims 9, 11-19, 20 and 22 depend from and contain all of the limitations of claim 8 and are therefore patentable for the same reasons as is claim 8. Claim 9 is a particularly preferred embodiment of the invention which recites preferred film formers for use in the invention. Dependent claim 12 describes a further embodiment of the invention which specifies a desired amount of the film former in the dual phase compositions. Dependent claim 13 calls for a preferred combination of oils in the oily phase of the composition.

CONCLUSION

One skilled in the art, seeking to formulate a dual phase cosmetic composition, comprising an oily phase and an aqueous phase, and a novel demixing agent, which composition emulsifies rapidly and uniformly upon vigorous shaking and demulsifies completely upon resting, would not have been led by the combined teachings in the references to arrive at the present invention.

The '496 reference discloses a two phase composition, comprising an aqueous phase and an oily phase, which is mixed and rapidly demixed with each use. However, the reference does not disclose or suggest the use of a film former as a demixing agent. The '155 reference describes a product including two miscible aqueous compositions; one being a color composition and the other a gel composition. The product is packaged to highlight the critical color emphasis of the color composition. The reference teaches using, in the color composition, a protective colloid, e.g. a film former, as a dispersing/suspending (i.e. stabilizing) agent for a substantial amount of pigment, and for preventing the pigment from bleeding into the gel phase. One skilled in the art would not have been led to introduce the protective colloid of the '155 reference into the dual phase composition of the '496 reference, since the '155 reference teaches/suggests using the protective colloid only to disperse/suspend a substantial amount of pigment in an aqueous phase, and there is no suggestion in the references of any advantage to introducing a substantial amount of a colorant to the compositions of the '496 reference. Moreover, the addition of a further stabilizing agent in the form of a film former would be expected to stabilize the emulsion form of the product, thus interfering with the demixing capability of the two phase composition.

The '758 reference describes a two phase cleansing composition, comprising an aqueous phase and an oily phase, which is mixed and rapidly demixed with each use; however, the reference does not disclose or suggest the use of a film former as a demixing agent. The '095 reference is concerned with a conditioning product comprising two distinct and separately packaged compositions which are combined only at the time of use, and never demixed. One composition is aqueous and contains a cationic conditioning agent, which may include film formers. The other composition is an oily composition. As the '095 reference teaches the separation of the cationic conditioning agents from the oily phase until the time of use, so as not to compromise the efficacy of the cationic polymers as conditioning agents, one skilled in the art would not have been motivated to introduce the cationic conditioning agents of the '095 reference into the dual phase composition of the '758 reference. One of ordinary skill in the art would predict that the repeated mixing and demixing of the proposed dual phase composition would effectively subject the cationic polymer in the aqueous phase to repeated contact with the oily phase such that the conditioning benefit imparted to the composition by the cationic polymer would quickly become negligible.

In light of the arguments presented herein, the obviousness rejections of claims 1, 2, 4, 5, 7-9 and 11-19, based on the '496 reference in view of the '155 reference, and the obviousness rejections of claims 1, 2, 4, 5, 7, 8 and 10-22, based on the '758 reference in view of the '095 reference, should be reversed as they are unfounded. Accordingly, the Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,

Date: _____

Cynthia R. Miller, Esq., Reg. No. 34,678
The Estee Lauder Companies Inc.
155 Pinelawn Road, Suite 345 South
Melville, N.Y. 11747
Tel. (631) 414-6068

CLAIMS APPENDIX

1. A dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent an effective amount of a film forming agent.
2. The composition of claim 1 in which the film forming agent is selected from the group consisting of non-cationic copolymers of vinylpyrrolidone.
3. The composition of claim 2 wherein the film forming agent is polyvinylpyrrolidone hexadecene copolymer.
4. The composition of claim 1 in which the demixing agent is present in an amount of from about 0.001 to about 10 percent by weight of the total composition.
5. The composition of claim 4 in which the demixing agent is present in an amount of from about 0.01 to about 1 percent by weight of the total composition.
7. The composition of claim 1 in which the aqueous phase and oil phase are present in a ratio of from about 40:60 to about 60:40, by weight of the total composition.
8. A liquid dual phase makeup removal composition comprising an oil phase and an aqueous phase in which the oil phase and aqueous phase are present in a ratio of from about 30:70 to about 70:30 by weight of the total composition, each phase being separate from the other before and after being mixed at the time of use, the composition containing as a demixing agent, an effective amount of a non-cationic film forming agent.
9. The composition of claim 8 wherein the film forming agent is selected from the group consisting of non-cationic copolymers of vinylpyrrolidone, acrylic acid polymers and non-cationic copolymers of acrylic acid.
10. The composition of claim 9 in which the agent is polyvinylpyrrolidone hexadecene copolymer.
11. The composition of claim 8 in which the agent is present in an amount of from about 0.001 to about 10 percent by weight of the total composition.

12. The composition of claim 11 in which the agent is present in an amount of from about 0.01 to about 1 percent by weight of the total composition.
13. The composition of claim 8 in which the oil phase contains a combination of volatile and non-volatile oils.
14. The composition of claim 13 in which the amount of volatile oil is about 30 to about 70 percent by weight of the total composition and the amount of non-volatile oil is about 0.1 to about 10 percent by weight of the total composition.
15. The composition of claim 13 in which the volatile oil is a volatile hydrocarbon.
16. The composition of claim 15 in which the volatile hydrocarbon is isododecane, isohexadecane, or a combination thereof.
17. The composition of claim 13 in which the volatile oil comprises both a volatile silicone and a volatile isoparaffin.
18. The composition of claim 17 in which the volatile silicone is cyclomethicone and the volatile isoparaffin is a C₁₆ isoparaffin.
19. The composition of claim 13 in which the non-volatile oil comprises a non-volatile silicone.
20. The composition of claim 19 in which the silicone is dimethicone.
21. The composition of claim 1 wherein the demixing agent is present in the oil phase.
22. The composition of claim 8 wherein the demixing agent is present in the oil phase.

EVIDENCE APPENDIX

No evidence is presented.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings or decisions.